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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,236	09/24/2003	Allen House	LIFE-011CON	8136
24353	7590	05/17/2006	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			HANDY, DWAYNE K	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/671,236	Applicant(s) HOUSE ET AL.	
	Examiner Dwayne K. Handy	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 21-29 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-7 of U.S. Patent No. 6,652,814 in view of Naka et al. (6,325,975). As noted in the previous rejection, claims 4-7 recite a test strip meter system comprised of a meter, a test strip and a test strip holder having a bump and a lip. Claim 3 recites the force applied by the lip and bump elements when the strip is inserted. Claims 3-7 of '814 teach every element of claims 21-29 except for the test strip having a compressible bladder, sample port, channel, and measurement area. Naka teaches a test strip comprised of 4 films. The strip includes a compressible

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bladder (suction generating area - 1), a drawing channel (2), a sample port (9), and a measurement area (3). Naka teaches the use of the suction generating as a means to draw the sample into the analysis area upon loading the strip (column 3, lines 20-30). It would have been obvious to one of ordinary skill in the art to combine the test strip of Naka with the device of Pat. No. '814. One would add the test strip of Naka in order to obtain a test strip that automatically loads the sample by suction simply by inserting the strip into the meter.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 21-24, 31, 32 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Naka et al. (6,325,975). Naka teaches a sample analysis device and suction generation means for the device. The device is best shown in Figures 3, 4A and 4B. The device includes a strip holder (bottom plate 63) having a lip (631) with an opening (632), a bladder actuator (portion 642 on operations plate 64), and a test strip (Figure 2) having a sample port, a channel, a measurement area, and a compressible bladder. Naka teaches the use of optical analysis means in column 4, lines 40-54; col. 7, lines 60-65; and col. 9, lines 19-25. The Examiner considers optical analysis means

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as meeting the limitation of the "meter" portion of the instant device. Naka discloses blood analysis at column 6, line 60 - column 7, line 6.

Inventorship

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 25-28, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naka et al. (6,325,975) in view of Hones et al. (5,424,035). Naka teaches every element of claims except for a raised bump for contacting a surface of the test strip. Hones teaches a test strip analysis system. The system includes a test strip holder (3). The strip holder includes a retaining lug (26) – a bump – that serves as both a support and a fixing element for fixing the position of the test strip. It would have been obvious to one of ordinary skill in the art to combine the retaining lug (bump) from Hones with the device of Naka. One would add the retaining lug to fix the location of the test strip for analysis. As to the amount of force provided by the lug (bump) with the lip, it would have been obvious to one of ordinary skill in the art to provide sufficient force to fix the test strip on the holder.

8. Claims 29 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naka et al. (6,325,975) in view of Gassenhuber (4,934,817). Naka teaches every element of claims 29 and 34 except for the holder being removable from the meter. Gassenhuber teaches a test strip evaluation system having a removable test strip holder (18). This allows the user to both clean the holder to prevent contamination as well as calibrate the device before inserting a strip (column 1, lines 40-61). It would have been obvious to combine the removable strip holder from Gassenhuber with the

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device of Naka. One would add a removable strip holder in order to be able to clean the holder and calibrate the device as suggested by Gassenhuber.

9. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Naka et al. (6,325,975) in view of Shartle (6,084,660). Naka teaches every element of claim 33 except for measuring clotting time. Shartle teaches a test strip system and method for measuring clotting time (column 5) using a test strip. It would have been obvious to combine the blood clotting analysis step with the method of Naka. One would add this step in order to perform a blood-clotting test. Blood clotting tests are well known in the art and one would wish to perform as many analyses as possible on a sample in order to save sample processing time.

Response to Arguments

10. Applicant's arguments, filed 2/27/06, with respect to all of the previous rejection(s) have been fully considered and are persuasive. Applicant has amended the claims to include a test strip having a sample port, channel, measurement area and bladder as well as a bladder actuation element. These features were not present in the previously cited Prior Art. Therefore, the previous rejections have been withdrawn. However, upon further consideration, new ground(s) of rejection have been made. The Examiner believes the addition of the new reference "Naka" contains the features in the new amended claims.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

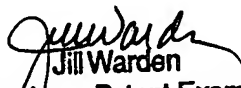
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DKH
May 15, 2006


Jill Warden
Supervisory Patent Examiner
Technology Center 1700